

REMARKS

Claims 1-10, 18, and 19 are currently pending. Claim 1, 9, 10, and 18 are amended. Support for the amendment to claims 1 and 18 may be found throughout the specification, for example, at page 7, lines 24-28. Support for the amendment to claims 9 and 10 may be found throughout the specification, for example, at page 5, lines 22-28 and page 11, lines 16-17. No new matter is being added by these amendments.

The present Office Action objects to the allegedly improper use of the trademark "Syloid" in the specification and claims. Instances of "Syloid" have been amended to include the generic terminology. Further, other minor typographical errors have been corrected. No new matter has been added.

On the merits, Claims 1-8 were rejected under Section 102(e) as allegedly anticipated by US 7,271,269 to Antoncic et al. ("Antoncic"). Claims 1-3 and 18-19 were rejected as allegedly obvious over US 2004/0006237 to Dolitzky et al. ("Dolitzky") taken in combination with US 5,608,075 to Campbell et al. ("Campbell") and Antoncic. Claims 9-10 were rejected as allegedly obvious over Antoncic in view of US 2006/0177498 to Bharatarajan et al. ("Bharatarajan"). Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

Rejection of Claims 1-8 As Allegedly Anticipated by Antoncic

Claims 1-8 stand rejected under Section 102(e) as allegedly anticipated by US 7,271,269 to Antoncic et al. ("Antoncic").

Claim 1 defines a pharmaceutical composition comprising, among other things, an active pharmaceutical ingredient in a first polymorph form susceptible to degradation or interconversion into one or more other polymorph forms, and a stabilizing substance selected from the group consisting of colloidal silicon dioxide, finely divided silicon dioxide, silicified microcrystalline cellulose, magnesium oxide, polyethylene glycol and croscarmellose sodium and, optionally, one or more pharmaceutically acceptable

excipients, wherein the stabilizing substance is present in an amount from about 1 % to about 10 % by weight of the pharmaceutical composition. The last proviso about the weight percent of the stabilizing substance is new to Claim 1. It avoids any alleged anticipation of Antoncic.

Antoncic does not disclose the use of a stabilizing substance in the range of from about 1 % to about 10 % by weight of the pharmaceutical composition. In the below table, it is shown that the stabilizing substance described in Examples 52a and 52b are actually said to be present in an amount of 0.95 wt%.

Antonicic, Example 52a	Weight, mg	component wt% / composition wt%	component wt% / finished dosage composition wt%
Losartan potassium	100	29.76	29.74
silica colloidalis anhydrica	3.2	0.95	0.95
Composition weight total	336		
Finished dosage weight total (plus 0.22 mg talc)	336.22		
Antonicic, Example 52b			
Losartan potassium	100	29.76	29.74
silica colloidalis anhydrica	3.2	0.95	0.95
Composition weight total	336		
Finished dosage weight total (plus 0.22 mg talc)	336.22		

Therefore, Antonicic cannot lawfully anticipate Claim 1 as amended. Claims 2-8, being dependent upon claim 1, are likewise not anticipated.

Rejection of Claims 1-3 and 18-19 As Allegedly Obvious from Dolitzky in view of Campbell and Antonicic.

Claims 1-3 and 18-19 stand rejected as allegedly obvious from US 2004/0006237 to Dolitzky et al. ("Dolitzky") taken in combination with US 5,608,075 to Campbell et al. ("Campbell") and Antonicic.

Independent Claim1 defines a pharmaceutical composition comprising, among other things, an active pharmaceutical ingredient in a first polymorph form susceptible to degradation or interconversion into one or more other polymorph forms and a stabilizing substance selected from the group consisting of colloidal silicon dioxide, finely divided

silicon dioxide, silicified microcrystalline cellulose, magnesium oxide, polyethylene glycol and croscarmellose sodium and, optionally, one or more pharmaceutically acceptable excipients, wherein the stabilizing substance is present in an amount of from about 1 % to about 10 % by weight of the pharmaceutical composition. Independent Claim 18 defines a method for treating hypertension and /or chronic renal failure comprising, among other things, administering to a patient in need thereof a pharmaceutical composition comprising an active pharmaceutical ingredient in a first polymorph form susceptible to degradation or interconversion into one or more other polymorph forms and a stabilizing substance selected from the group consisting of colloidal silicon dioxide, finely divided silicon dioxide, silicified microcrystalline cellulose, magnesium oxide, polyethylene glycol and croscarmellose sodium and, optionally, one or more pharmaceutically acceptable excipients, wherein the stabilizing substance is present in an amount from about 1 % to about 10 % by weight of the pharmaceutical composition.

None of the cited references, Dolitzky, Campbell, or Antoncic discloses, teach or suggest a composition or method comprising a stabilizing substance present in an amount from about 1 % to about 10 % by weight of the pharmaceutical composition. Dolitzky does not give any disclosure of any amounts of any excipients. Campbell discloses the preparation of a tablet, however, the amounts do not fall within the present claim scope. See the table below.

Campbell, Column 22, Tablets Example	Weight, mg	component wt% / composition wt%
Active Ingredient	100	20.4
colloidal silicon dioxide	0.2	0.0
magnesium stearate	5	1.0
Microcrystalline cellulose	275	56.1
Starch	11	2.2
Lactose	98.8	20.2
Composition weight total	490	

And, as discussed above, Antoncic also does not disclose the claimed range of stabilizing substance. Therefore, even with the combination of the three cited references, the present claims are not disclosed and likewise not made obvious.

Also, Antoncic is not citable against the claims in this case due to application of 35 U.S.C. § 103(c). Both this case and Antoncic are owned by the same entity or subject to an obligation to assign to the same entity (LEK Pharmaceuticals) and Antoncic is cited as prior art under 102(e). Thus, no part of Antoncic may properly be cited against the present claims, which plainly and undisputedly patentably distinguish over Dolitsky and Campbell.

The present claims 1 and 18 and their dependent claims therefore patentably distinguish over the cited combination of Dolitzky, Campbell, and Antoncic, which, even though not shown to be “obviously” combinable, nevertheless fail to disclose, teach, or suggest the subject matter of these claims.

Rejection of Claims 9-10 As Allegedly Made Obvious by Antoncic in view of Bharatarajan

Claims 9-10 are rejected as allegedly being obvious over Antoncic in view of US 2006/0177498 to Bharatarajan et al. (“Bharatarajan”).

As discussed above, Antoncic is not properly citable against the present claims according to the dictates of 35 U.S.C. § 103(c) but, in any event, it does not disclose the claimed range of stabilizing substance. In fact, Antoncic discloses using only a very small amount of what is said to be a stabilizing substance. (See the table presented above). On the other hand, Bharatarajan is not directed to the same active ingredient as Antoncic, and therefore would not be “obviously” combined with Antoncic in any event. One of skill in the art would not consult literature describing a completely different active ingredient. Further, there would be no motivation to do so after reading Antoncic. Antoncic does not indicate that the disclosed formulations shown in Examples 52a and 52b would be “unstable.” It is only after considering Applicant’s present specification that one would be led to methods to stabilize the crystallinity of the claimed active ingredient susceptible to degradation or interconversion into other polymorph forms. The mere fact that Bharatarajan discloses stabilizing a completely

different pharmaceutical (i.e., ramipril) does not provide a motivation to stabilize according to Applicants' claims, especially since Antoncic would not be in the picture by virtue of § 103 (c). Therefore, the present Claim 1 and its dependent claims, 9 and 10 are nonobvious in view of the cited references.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

A request for a one-month extension of time for reply is requested. Therefore, please charge the fee for a one-month extension in the amount of \$120.00 to **Deposit Account No. 12-2355**. In the event these calculations are incorrect, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this submission be charged to our **Deposit Account No. 12-2355**.

Respectfully submitted,

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Date: July 10, 2008
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